

BCG vaccine and post-BCG complications among infants in Gaza Strip, 1999

R. Awad¹

لقاح بي سي جي ومضاعفات التطعيم به بين الأطفال الرضع في قطاع غزة، 1999

رياض عبد الكريم عواد

خلاصة: تم بحث العلاقة بين المضاعفات التالية للتطعيم بلقاح بي سي جي وبين طرائق التطعيم، أو استعمال دفعات إنتاجية معينة من هذا اللقاح، أو كليهما. وقد وُزِع استبيان على الممرضات اللائي يقمن بالتطعيم. واستُخدمت صحيفة تلخيصية لتحليل حالات الإصابة بمضاعفات تالية للتطعيم بين الرضع (وعدددهم 552 رضيعاً) وبين تلاميذ المدارس (وعدددهم 97). وقد بلغ معدل حدوث المضاعفات 19.1 في الألف في مراكز الأنروا الصحية و8.3 في الألف في المراكز الحكومية. وتبين أن دفعة إنتاجية واحدة من بي سي جي 11-2611، استعملت بطريقة خاطئة، كانت سبب وقوع هذه الفاشية من المضاعفات. وبناء عليه، يقتضى الأمر إقامة نظام للرصد من أجل رصد ما يقع بعد التطعيم من عقابيل.

ABSTRACT The relationship between post-BCG complications and the practices of administration and/or use of certain batches of BCG vaccine was investigated. A questionnaire was given to nurses administering BCG vaccination. An abstraction sheet was used to analyse cases with BCG complications among infants ($n = 552$) and schoolchildren ($n = 97$). The rate of complications was 14.7/1000 among infants and 2.5/1000 among schoolchildren in 1997. The complications rate was 19.1/1000 at UNRWA and 8.3/1000 at governmental health services. It was found that a single batch of BCG 2611-11 combined with incorrect administering of the vaccine was responsible for this outbreak of complications. Therefore, the establishment of a surveillance system to monitor adverse events following immunization is needed.

Le vaccin BCG et les complications survenant après le BCG chez des nouveau-nés dans la bande de Gaza, 1999

RESUME La relation entre les complications survenant après le BCG et les pratiques d'administration et/ou d'utilisation de certains lots de vaccins BCG a été examinée. Un questionnaire a été donné aux infirmières qui administrent la vaccination BCG. Un formulaire d'abstraction a été utilisé pour analyser les cas comportant des complications liées au BCG chez les nouveau-nés ($n = 552$) et les enfants scolarisés ($n = 97$). Le taux de complications était de 14,7/1000 chez les nouveau-nés et de 2,5/1000 chez les enfants scolarisés en 1997. Il était de 19,1/1000 à l'UNRWA et de 8,3/1000 dans les services de santé gouvernementaux. On a trouvé qu'un seul lot de BCG 2611-11 associé à une administration incorrecte du vaccin était responsable du déclenchement de ces complications. Il est donc nécessaire de mettre en place un système de surveillance pour faire le suivi des réactions postvaccinales indésirables.

¹Department of Epidemiology, Ministry of Health, Rimal Clinic, Gaza, Palestine.

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Introduction

Tuberculosis (TB) is still a public health problem in developing countries. Its most serious complication in children is meningoencephalitis (ME-TB), which is one of the main causes of death from TB [1]. In the Eastern Mediterranean Region (EMR), TB is an important public health problem. It is estimated that 30% of the region's population is already infected with tuberculous bacilli. The estimated annual incidence of TB in 1995 was 166 per 100 000 population [2]. EMR countries can be classified into three groups according to their incidence of pulmonary TB. Palestine is one of the EMR countries in the third group, characterized by a low incidence (< 20/100 000) [2].

The principal objectives of post-marketing surveillance are the early detection of adverse events following immunization and the ability to offer an appropriate and rapid response to such events to lessen their negative impact on health and on the immunization programme. An adverse event is "an untoward event, temporarily associated with immunization, that might or might not be caused by the vaccine or the immunization process". Only three of the EMR countries conduct post-marketing surveillance: a functional system has been established in Oman since 1996, while Egypt and the Syrian Arab Republic started their programmes in 1998 [3].

Vaccine complications have an adverse effect on the uptake of immunization in Palestinian children [4]. The World Health Organization and United Nations Children's Fund (WHO/UNICEF) have recommended that developing countries choose a vaccine supplier who can reliably supply the quality of vaccine to meet the necessary standards [4].

This study had four objectives: first, to estimate the reported incidence of post-bacille Calmette-Guérin (BCG) complications by age and area of residence; second, to compare the rate of post-BCG complications in different health care centres; third, to determine the risk factors associated with post-BCG complications; fourth, to establish a surveillance system for adverse events following immunization (AEFIs).

Methods

This is a descriptive study, retrospectively reviewing subjects diagnosed with post-BCG complications by different health providers and facilities. The researcher visited all 28 maternal and child health (MCH) centres where BCG vaccination is carried out and observed the vaccination technique and reporting. A questionnaire was used to collect data from all nurses responsible for BCG vaccination.

In Gaza Strip, it was vaccination policy before 1999 to vaccinate all neonates at the first visit to the MCH centre and to give the second dose to schoolchildren in their first year of school. In the years 1997 and 1998 in Gaza Strip, 37 463 and 36 462 infants were vaccinated with BCG vaccine. The number of schoolchildren vaccinated with BCG in the school year 1997-98 was 38 739. All infants and schoolchildren who developed post-BCG complications were included in the study. In 1997, about 552 post-BCG complications among infants and 97 post-BCG complications among first-year schoolchildren (6-7 years old) were reported. The cases were from different districts and environmental areas (urban, rural, refugee camp) of Gaza Strip. An abstraction sheet was used to collect the required data on eligible children. The study also included nurses who admi-

nistered BCG vaccination in the period concerned. The researcher interviewed these nurses using a structured questionnaire in Arabic with closed questions.

Confidentiality was maintained at all times during the study of the nurses. All participants gave their informed consent in Arabic. SPSS was used for data entry and analysis. Data were tested for statistical significance using the chi-squared test, with *P*-value considered statistically significant at the 0.05 level.

Results

Post-BCG vaccine complications

A total of 552 cases of complications occurred in 1997 and 48 in 1998. Between January and March 1997, 4–10 cases were reported a month. In April 1997, 31 cases were reported, and the number of cases increased suddenly in July and August 1997 to 130 and 121 cases respectively. In September and October 1997, 50 and 34 cases were reported. The number of cases then dropped sharply in November and December 1997 to 2 and 0 cases respectively. Post-BCG complications continued to be reported in 1998 in numbers ranging from 0 cases in January 1998 to 3–5 cases in the following months until September when 7 cases were reported; thereafter until the end of the year there was 1 case reported per month.

The annual rates of complications in vaccinated infants were 14.7/1000 and 1.3/1000 in 1997 and 1998 respectively. The rate was higher (19.1/1000) at the United Nations Relief and Works Agency for Palestinian Refugees in the Near East (UNRWA) than at the government health services (8.3/1000).

Distribution of complications

The Midzone district (including Deir El-Balah and refugee camps) showed the highest rate of complications (25.2/1000) and Gaza City district the lowest (10.3/1000). The rates of complications in the other three districts (Rafah, Khan Younis and the North district) were 19.4/1000, 17.2/1000 and 11.3/1000 respectively. The difference between the different districts was statistically significant ($P < 0.001$). Complications were reported by all MCH centres, with rates ranging from 38.5/1000 at UNRWA Buraje MCH centre to 2.9/1000 at the Bander Gaza government MCH centre. The rate of complications was more than 20/1000 at nine MCH centres; seven of these were run by UNRWA health services.

The age distribution of children with complications showed that about 222/1000 of post-BCG vaccine complications occurred during the first week of life. The rate dropped in the following weeks from 19/1000 in the second week to 2.1/1000 and 6.9/1000 in the third and fourth weeks of life respectively. The odds ratio was calculated to compare the rate of complications for different ages at which BCG vaccination was received. There was a statistically significant relationship between the onset of complications and receiving BCG vaccination during the first week of life. The distribution of post-BCG vaccine complications among infants showed no statistically significant difference between the sexes ($P = 0.07$). Lymphadenitis accounted for about 98% of complications; the remaining 2% were abscess and ulceration at the site of the BCG injection. No cases of osteitis were detected among infants in the study period.

Table 1 Rate of complications for different vaccine batches 1997 (n = 501)

Batch No.	Complications	Doses	Complications/ batch (per 1000)	Odds ratio (CI)
N5221-1	6	1 600	3.8	0.50 (0.20–1.16)
329011A	4	6 000	0.7	0.08 (0.03–0.23)*
1651B	16	14 180	1.13	0.13 (0.07–0.21)*
2611-11	443	22 800	19.4	2.64 (2.35–3.06)*
9656	28	22 300	1.3	0.12 (0.08–0.18)*
M6435-1	4	1 200	3.3	0.45 (0.14–1.24)
Total	501	68 080	7.4	

*Significant at 0.05 level.
CI = confidence interval.

There was no statistically significant difference ($P = 0.59$) between the rates of post-BCG vaccine complications among low-birth-weight infants (8.4/1000) and normal-weight infants (7.17/1000).

Rate of complications for different BCG batches

The BCG vaccine batches used for infant vaccination in 1997 were 2611-11, N5221-1, M6435-1, 9656, 1651B, and 329011A (Table 1). The odds ratio was calculated to compare the rate of complications for each batch with the average rate of complications for all batches. The only batch associated with a statistically significant raised rate of complications was batch 2611-11.

Nurses' knowledge and practices of BCG administration

Table 2 shows that about two-thirds (63%) of the nurses knew the correct dose of BCG vaccine for an infant. However, 37% of nurses did not know the correct dose. Of these, 41% were working at UNRWA and 33% at government health centres ($P =$

0.041). About 53% did not know that BCG is contraindicated for an infant born of a mother positive for human immunodeficiency virus (HIV), while 47% did not give BCG vaccine to infants from mothers infected with tuberculosis. About 59% of nurses did not know that BCG vaccination is not effective against all types of TB with statistically significant difference between UNRWA and government nurses ($P < 0.001$). About 42% of the nurses postponed vaccination for icteric infants; of these, 15% and 64% respectively were working at UNRWA and government health centres, and these figures showed a statistically significant difference ($P < 0.001$). About 15% of the nurses at the UNRWA health centres completed the administration of the vaccine if the needle was inserted subcutaneously. About 29% of the nurses repeated the dose if there was no nodule formation; the proportion varied from 41% at UNRWA to 19% at government health centres. About 17% of nurses at government health centres used disinfectant before vaccination (Table 2).

Table 2 Nurses' knowledge and practices of BCG administration (n = 76)

Question	UNRWA		Government		Total		P-value ^a
	No.	%	No.	%	No.	%	
<i>What is the correct dose for an infant? (mL)</i>							
0.05	20	58.8	28	66.7	48	63.0	0.040
0.5	13	38.3	6	14.3	19	25.0	
0.1	1	2.9	8	19.0	9	12.0	
<i>Is BCG given to infants of HIV-positive mothers?</i>							
Yes	19	55.9	21	50.0	40	53.0	0.740
No	15	44.1	21	50.0	36	47.0	
<i>Is BCG given to infants of mothers infected with TB?</i>							
Yes	19	56.0	25	59.0	44	58.0	0.650
No	15	44.0	17	41.0	32	42.0	
<i>Does BCG protect against all types of TB?</i>							
Yes	20	59.0	25	60.0	45	59.0	0.001
No	14	41.0	17	40.0	31	41.0	
<i>Should BCG be postponed for icteric infants?</i>							
Yes	5	15.0	27	64.0	32	42.0	0.001
No	29	85.0	15	36.0	44	58.0	
<i>If there is no nodule, do you repeat the vaccination?</i>							
Yes	14	41.0	8	19.0	22	29.0	0.110
No	20	59.0	34	81.0	54	71.0	
<i>If the needle is inserted subcutaneously, what do you do?</i>							
Complete	5	14.7	0	0.0	5	7.0	0.015
Stop	29	85.3	42	100.0	71	93.0	
<i>Do you disinfect before BCG vaccination?</i>							
Yes	0	0.0	7	17.0	07	9.0	0.114
No	34	100.0	35	83.0	69	91.0	

^aBy Fischer exact test.

BCG = bacille Calmette-G urin.

UNRWA = United Nations Relief and Works Agency for Palestine Refugees in the Near East.

HIV = human immunodeficiency virus.

TB = tuberculosis.

Discussion

The results of this study are unique in providing detailed documented information on post-BCG complications and their possible causes in Gaza Strip. They demonstrate very convincingly that a single batch of BCG vaccine, batch 2611-11, was responsible for the increased rate of complications among infants in Gaza Strip in 1997.

BCG vaccine policy and coverage

In a study in Italy, about half the mothers (45.2%) correctly thought that the undesirable side-effects of vaccination were a more important determinant of its value than whether it protected the infants from getting disease [5]. To our knowledge, however, surveillance data on AEFI in Palestine are not available and such information is urgently needed.

WHO does not recommend repeating BCG vaccination because there is no scientific evidence to support this practice [6]. In 1995, 19 of the 23 countries in the EMR vaccinated infants against TB using the BCG vaccine. The four exceptions were Cyprus, Jordan, Kuwait and Lebanon [7]. In Palestine, the two-dose policy of BCG vaccination was changed in January 1999 so that only one dose of BCG is now provided for infants.

In 1995, BCG coverage among infants in the EMR ranged from 44% in Afghanistan, 55% in the Republic of Yemen, 91% in Palestine, 93% in Egypt, to 100% in the Syrian Arab Republic [8]. Our findings show that BCG coverage among infants in Gaza Strip dropped from 97.0% in 1997 to 81.0% in 1998. Coverage varied by district, with the North district showing the lowest coverage where it dropped from 85.2% in 1997 to 81.0% in 1998. The factors that may affect immunization coverage need to be identified and addressed in order to reduce the noncompliance rate. BCG vaccination is the cornerstone of the immunization programme. If infants miss out on this, the immunization schedule for other diseases could be affected. The question of when BCG vaccination may be stopped without adverse consequences is under consideration by WHO [9]. In Gaza Strip, there has been a steady decline in the reported cases of pulmonary TB which reached 1.56/100 000 in 1997 and 0.8/100 000 in 1998 [10]. Decision-makers should develop new protocols for BCG vaccination more appropriate to existing conditions.

Efficacy of BCG vaccine

Ten Dam and Hitze demonstrated that BCG efficacy varies widely and there are no reliable immunological markers of protection

against tuberculosis [11]. Efficacy in preventing pulmonary TB has ranged from zero in southern United States and in South India/Chingleput to approximately 80% in the United Kingdom. Data show that BCG also protects against meningitis tuberculosis and against miliary tuberculosis (estimated 75%–86% protection) [11].

Our findings showed that, although all participants knew the importance of BCG vaccination in general, 59% were not aware that there are differences in the efficacy of BCG vaccination against different types of TB, these differences being statistically significant. About 17% of nurses at government health service had been using disinfectant before BCG vaccination; this practice may have adverse effects on BCG efficacy.

Vaccine sources and cost

In 1996, the vaccine supply and quality unit was created by WHO's Global Programme for Vaccine and Immunization. Its aim is to rid the world of poor-quality vaccines. One-fifth to one-quarter of the 3 billion doses of vaccines used annually in national childhood immunization programmes are of unknown quality, mostly those used in the developing countries [12]. The cost of the six basic vaccine antigens per fully immunized child in developing countries is estimated to be US\$ 15. UNICEF estimated that US\$ 1 covers the cost of the basic vaccines against tuberculosis, poliomyelitis, tetanus, diphtheria, whooping cough and measles; the remaining US\$ 14 represents the cost of their administration, delivery and other logistical expenses [13]. In 1999, although these vaccines for use in Palestine were purchased directly from WHO, their cost, at US\$ 1.7, was higher than WHO estimates. This higher cost may be due to a high proportion of vaccine wastage and the

use of single dose presentation of vaccines, e.g. measles vaccine is frequently supplied in a single-dose presentation [14]. The total cost of vaccines for the basic and school-children's immunization programme was US\$ 720 777 when purchased directly from WHO and US\$ 2 070 987 when purchased from a local agency: US\$ 1 352 210 (65% of total cost) were therefore saved.

BCG vaccine wastage

Vaccine wastage rates of up to 50% are not unusual for the traditional low-cost vaccines. The need to reduce wastage is therefore critical [15]. The percentage of BCG vaccine wastage as a proportion of doses given for infant vaccination in Gaza Strip was 82%, about 55% at the UNRWA health service and 125% at government health services. Differences in wastage between government and UNRWA health services could be explained by the government sector's responsibility to ensure vaccine safety. In addition, part of the wastage may have been due to condemnation of BCG vaccine batch 2611-11.

BCG contraindications

Misconceptions about contraindications for vaccination were frequently indicated as a cause of unnecessary delay in administering vaccine [5]. The only valid reason not to give BCG vaccine is when there is a family history of primary immunodeficiency, i.e. combined or T-cell deficiency [16]. Study results show that 25% of nurses did not know the correct contraindications for BCG vaccination. About 53% did not know that BCG is contraindicated for an infant born of an HIV-positive mother, 29% did not give BCG vaccine to infants of mothers with TB and about 42% postponed BCG vaccination for icteric infants. Of the 42%,

14.7% worked at UNRWA and 64.3% in the government health service, a statistically significant difference ($P < 0.001$).

Distribution of BCG complications

An outbreak of post-BCG vaccination lymphadenitis was reported in the West Bank during June 1997. The incident was controlled after the incriminated batch of vaccine 2611-11 was replaced with another batch from a different source in July 1997. Unfortunately, a similar outbreak was building up in Gaza Strip in 1997 [17]. The outbreak confirmed that health services would continue to be affected as long as the borders between Gaza Strip and the West Bank remain sealed. It also reinforced the need to establish an AEFI disease surveillance system [17]. Had Gaza been aware of the West Bank's experience, the outbreak could have been controlled as early as mid-year. In fact the outbreak in Gaza Strip was only controlled when the incriminated batch 2611-11 was withdrawn at the end of October 1997. This emphasizes the importance of strengthening the communication link between Gaza Strip and the West Bank.

The rate of post-BCG complications at the UNRWA health service was 19.1/1000, higher than at the government health service at 8.3/1000. This was due first to the fact that 79.8% of the incriminated BCG vaccine batch 2611-11 was used for infant vaccination at the UNRWA health service. Second, active surveillance of post-BCG complications was implemented at UNRWA health centres by the Disease Control Office. Third, the nurses' techniques of administering BCG vaccination exacerbated the problem of post-BCG complications; for example 41% of nurses of UNRWA centres repeated the BCG vaccination if there was no nodule formation.

Risk factors associated with BCG complications

BCG strain

A number of studies report that the incidence of suppurative lymphadenitis changes when one vaccine is replaced by another. In Saudi Arabia, the incidence of regional lymphadenitis following BCG vaccination of neonates increased after the introduction of the Tokyo strain of BCG vaccine [18]. Our findings indicate that BCG vaccine batch 2611-11, which was found to have a high residual virulence, was strongly associated with the post-BCG complications that occurred among infants in Gaza Strip in 1997. This batch was manufactured by Connaught Laboratories, Willowdale, Ontario, Canada (a Pasteur Merieux Company), with expiry dates of October 1998 and December 1998.

BCG dose and administration

Although staff nurses had practised correctly administering (learning by doing) the BCG dose (0.05 mL) to infants, the study results show that 37% of the nurses did not know the correct dose of BCG vaccine. About 15% of nurses at the UNRWA health centres completed the dose of vaccine if the needle was inserted subcutaneously. About 29% of nurses repeated the dose of BCG vaccine if there was no nodule formation, 41% at UNRWA and 19% at government health centres.

Host characteristics

The major host characteristics that may affect adverse reactions to BCG vaccination are the age, weight and immune status of the individual [18].

The main characteristic associated with increased risk of lymphadenitis is an age of less than 1 month at immunization. The incidence of lymphadenitis among infants aged less than 1 month is approximately

twice that among those over 3 months of age [18]. Results of a study in the United States of America in 1996 indicate that post-BCG regional lymphadenopathy varies with age from 387 per million at age < 1 year to 52 per million at 1–20 years of age [16]. Our findings showed that in 1997 the rate of post-BCG vaccine complications was 14.7/1000 among infants and 2.5/1000 among first-year schoolchildren. Increased incidence of complications also occurred mostly among infants vaccinated with BCG vaccine in the first week of life, which may have been due to the difficulty of correctly administering BCG vaccine intradermally to infants.

Despite the advice on some vaccine package information sheets that a birth weight of less than 2500 g is a contraindication for BCG vaccination, there is no good evidence that moderately premature or low-birth-weight infants are at any increased risk of BCG vaccine complications [18]. Our findings show that the rates of post-BCG vaccine complications were 8.4/1000 among low-birth-weight infants (< 2500 g) and 7.17/1000 among normal-weight infants, with no statistically significant difference ($P = 0.59$). Thus there would appear to be no reason to delay BCG vaccination in low-birth-weight infants.

Recommendations

- An AEFI surveillance system should be established.
- Nurses should receive health education and continuous training on vaccination.
- Vaccination in general, and BCG vaccination in particular, should be closely supervised. Health workers should receive immediate feedback on their AEFI activities. When AEFIs are reported, supervision should be intensified.

- The recommended immunization schedule should be followed, especially for hepatitis B vaccination. Switching from one vaccine strain to another should be avoided. Special caution is required when one strain is replaced by another.
- A vaccine distribution protocol should be implemented. Vaccine wastage in general, and BCG vaccine wastage in particular, should be minimized.
- Vaccines should be purchased from an accredited source where there is confidence that the quality of the vaccines meets the necessary standard. It is preferable to purchase directly through United Nations agencies such as WHO and UNICEF.
- The cost of vaccines should be reduced to be consistent with WHO estimates.
- There is no reason to delay BCG vaccination for infants with low birth weight (< 2500 g), or for icteric infants. Infants of TB-infected mothers urgently need BCG vaccination. BCG is contraindicated only for immunodeficient patients (symptomatic HIV-positive infants and infants born of HIV-positive mothers).
- Cooperation between government and UNRWA health services in the immunization field should be strengthened.
- The Palestinian vaccination surveillance system should be strengthened, and coordination and communications between Gaza Strip and the West Bank improved.

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